Instructions for Paper Submission of Form FDA 2541 (Food Canning Establishment Registration) for an Acidified/Low-Acid Food Canning Establishment

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
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For additional information, see <u>FDA's website for LACF Registration</u>.

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I. Introduction

Commercial processors engaged in the manufacturing, processing, or packing of acidified foods (AF) and/or thermally processed low-acid foods packaged in hermetically sealed containers (historically referred to as "low-acid canned foods" or "LACF") are subject to the registration requirements of 21 CFR 108.25(c)(1) (for AF) or 21 CFR 108.35(c)(1) (for LACF), as well as the process filing requirements of 21 CFR 108.25(c)(2) (for processors of AF) or 21 CFR 108.35(c)(2) (for processors of LACF). There are two basic types of such required submissions:

- Food Canning Establishment Registration using Form FDA 2541; and
- Process filings using the following forms:
 - Form FDA 2541a (Food Process Filing for All Methods Except Aseptic)
 - Form FDA 2541c (Food Process Filing for Low-Acid Aseptic Systems)

This document provides detailed instructions on how to:

 Register a new Food Canning Establishment (FCE) by paper submission using Form FDA 2541;

- Change the preferred mailing address for the FCE;
- Change the list of products manufactured, processed or packed at the FCE; and
- Cancel registration for an FCE (e.g., if production ceases or there is a change in ownership).

¹ Although some hermetically sealed containers (e.g., pouches and glass bottles) used to package thermally processed low-acid foods generally would not be viewed as "cans," the term "low-acid canned foods" has been used for decades as a shorthand description for "thermally processed low-acid foods packaged in hermetically sealed containers," and we continue to use that term (and its abbreviation, LACF) for the purposes of this document.

This document does not provide instructions for submitting Form FDA 2541 in electronic format or for submitting process filing forms in either electronic or paper format. You can obtain information about submitting Form FDA 2541 in electronic format, and about submitting process filing forms in either electronic or paper format, from our guidance entitled "Guidance for Industry: Submitting Form FDA 2541 (Food Canning Establishment Registration) and Forms FDA 2541a and FDA 2541c (Food Process Filing Forms) to FDA in Electronic or Paper Format" (Ref. 1 and the appendices to Reference 1).

II. How to Submit Registration Form FDA 2541 by Paper

A. General Information

All commercial processors of low-acid and acidified foods located in the United States and all processors in other countries who export low-acid canned food or acidified food products into the United States must register their processing plants with FDA. Wholesalers, importers, distributors, brokers, etc. are not required to register and file processes. However, they must ensure that processing firms they represent comply with all registration and process filing requirements.

Low-acid canned food and acidified food processors in the United States must register with FDA not later than 10 days after first engaging in the manufacture, processing, or packing of acidified foods or of low-acid canned foods. Processors in other countries must register before offering any such products for entry into the United States.

PROCESS FILING FORMS WILL BE RETURNED FROM UNREGISTERED FIRMS. However, registration and initial process filing may be done at the same time.

To register with FDA, processors must complete and submit to FDA Form FDA 2541 for each processing establishment location according to these instructions.

We recommend that the authorized representative make and keep a copy of the registration form.

Form FDA 2541 contains 6 sections (Sections 1 through 6) of which Section 1 is for FDA use only and will be completed by FDA LACF Coordinator.

- All mandatory fields on Form FDA 2541 must be completed.
- Information you provide on Form FDA 2541 should be in English.

B. Section 1: Top of Form – For FDA Use Only

1. Food Canning Establishment (FCE) Number:

FDA will assign a Food Canning Establishment (FCE) number to the establishment being registered. A copy of the registration form will be returned to you with the FCE number

entered in the space labeled: "**FCE No.**" You should include that FCE number on all correspondence with FDA. It will assist in expediting inspection of entries into the U.S. if the FCE number is identified on all shipping documents for these products.

2. Date Received by FDA:

This is the date the completed registration form is received by FDA. This is for FDA use only and will be filled in by the FDA LACF Coordinator upon receipt.

C. Section 2: Type of Submission

There are several options available under this section of the form. Examples are available for completed forms in the Appendix.

Initial Registration

Check "Initial Registration" if this processing plant location has never been registered and continue to Section 3.

Relocation (new registration required)

Check "Relocation (new registration required)" if you have a previously registered FCE number and you are moving to a new location. Enter the current FCE in the space provided next to this option and continue to Section 3. Relocation of the facility will cancel the existing registration and all process filing forms under the old FCE number. New process filing forms must be submitted for the new location.

Change of Registration Information

Check "Change of Registration Information" if you are submitting changes such as the following for a previously registered firm:

- Change in firm name
- Change in mailing address
- Change in ownership* (New Registration Required)
- Change in postal address because of renaming of street, renumbering of building, etc. (no actual change in location).
- Cancellation of FCE

Specify Type of Change: Enter the change to the registration (e.g., cancellation, renaming of street, etc.) along with the current FCE number in the space provided. Refer to an example in the Appendix.

You are not required to provide changes to products no longer manufacturered, processed, or packed and/or for new products manufacturered, processed, or packed at the processing plant. You are required to submit process filing forms for new products manufacturered, processed, or packed as referenced in Section I - Introduction in this document.

* If there is a change in ownership, a new registration for the new ownership must be completed in addition to all process filing forms.

D. Section 3: Food Processing Plant Location

Establishment Name

Enter the name of your establishment as you want it to be registered. The name and address should be listed exactly as it appears on letterheads, stationary, invoices, shipping documents and labeling on products or detentions. Wherever possible, use standard abbreviations such as the following:

- Inc. for Incorporated
- Co. for Company
- Ltd. for Limited
- Corp. for Corporation

Number and Street

Enter the address of the **physical location** of the establishment where your products are manufactured, processed, or packed. Post Office (PO) Boxes are not considered a physical location of the establishment. Abbreviations such as the following may be used:

- St. for Street
- Dr. for Drive
- Ave. for Avenue
- Rd. for Road
- Ln. for Lane
- RR for Rural Route
- Blvd. for Boulevard

City and State or Province (or other Subdivision)

For establishments in the United States (US), enter the city and use the two-letter Postal Service abbreviation for your state. For countries other than the US, enter the city, subdivision, province, region, and any other pertinent information to identify the plant location (e.g., Abbotsford, Vancouver, British Columbia; Brooklyn, Victoria, Australia, etc.)

ZIP (or other Postal Code)

For establishments in the United States (US), enter the 9 digit zip code if one has been assigned; otherwise, enter the 5 digit code. For countries other than the US, enter the city, if a postal code has been established by the postal system of your country, enter that code.

Country

For establishments in the United States (US), leave this section blank. For countries other than the US, enter the name of the country in which your processing plant is located.

Telephone No.

For establishments in the United States (US), enter the 3 digit area code along with the 7 digit telephone number. For countries other than the US, enter the country code, city code, and telephone number.

Telefax No.

For establishments in the United States (US), enter the 3 digit area code along with the 7 digit fax telephone number. For countries other than the US, enter the country code, city code, and fax telephone number.

E. Section 4: Preferred Mailing Address

You have two options of where to send all correspondence from FDA. If you want all correspondence to be sent to the same address as referenced in Section 3 – Food Processing Plant Location, then select the box "Same as Plant Location" and leave this section blank. If, however, you want all correspondence from FDA to be sent to an address different than your plant location address, enter the preferred mailing address in the spaces provided. Use the same guidelines referenced in Section 3 of this document except that you may enter a Post Office (P.O.) box number instead of number and street, if applicable.

NOTE: This preferred mailing address will be used for all FDA correspondence regarding registration and process filing. Therefore, if registration and process filing is handled by someone located in a firm's headquarters, research lab, etc., that address should be listed and all FDA mailings will be sent there.

F. Section 5: Low Acid and/or Acidified Foods Processed at this Location.

This section should list all products manufactured at the processing plant and identify the products as low-acid or acidified in the check box adjacent to the product name.

Some examples of product names:

- Cheese sauce
- Soy sauce
- Tuna in brine
- Artichokes in oil

G. Section 6: Facility Contact Person

A Facility Contact Person (FCP) should be an authorized, responsible official located at the processing plant. Enter the first and last name of the person authorized to represent the facility, as well as the facility name and address of the authorized representative.

Check the appropriate box for "Position held at Plant Location" of the FCP and the FCP phone and fax number, and email address. The person authorized to represent the facility must sign and date the form.

III. How to Contact FDA or Obtain Help

You may contact us:

- By Email at LACF@fda.hhs.gov;
- By telephone at 240-402-2411; and
- By mail at the address immediately below.

Food and Drug Administration LACF Registration Coordinator (HFS-303) Center for Food Safety and Applied Nutrition 5100 Paint Branch Parkway College Park, Maryland 20740-3835

IV. References

1. <u>Guidance for Industry: Submitting FDA Form 2541 (Food Canning Establishment Registration) and FDA Forms 2541a and 2541c (Food Process Filing Forms) to FDA in Electronic or Paper Format</u>

V. Appendix

A. Examples of Completed FDA 2541 Registration Form

Figure 1 – Example of FDA 2541 for a New Registration

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Figure 2 - Example of FDA 2541 Relocation of Establishment

DEPAR	RTMENT OF HEALTH A	AND HUMAN S	ERVICES	-		USE ONLY
TYPE OF SUBMISSION 2	Food and Drug As ANNING ESTABLISI		ICTRATION	FCE No.	FORFDA	Date Received by FDA
initial Registration		HMENT REG	ISTRATION			
Relocation (new registration required) Enter Current FCE: (If applicable) 000	003					
Change of Registration Information Enter Current FCE: (if applicable)						
Specify Type of Change: processing plant moved						
FOOD PROCESSING PLANT LOCATION 3	P	REFERRED	MAILING ADD	RESS Sa	me as Plant Lo	ocation 4
XYZ Co.		X	YZ Co.			
1111 North St.			Main St.			
City and State or Province		ity and State r Province				
or Province (or other Subdivision) Abbotsford, Vancouver, British Columbia	(0	or other Subdivis	sion) Abbotsfor	d, Vancouver, Bri	itish Columbi	II.
VT2 6W3 Canada		V	r2 6W3	Canad	a	
	T THIS LOCATION Medium cess fling.		The requester making this re Section 1001, conceal, or co statement or r the same to c Subject to the commercial per	FE THE FOLLOW hereby presents an quest the company I united States Code ere up a material fac apresentation; or ma initial any materially terms of 21 CFR 10 ocessor shall engag	MING: d acknowledge is subject to the which makes I ct; make any Is ske or use any v false, fictitious 8.25 (c)(1) and se in the proces	I 555 111 9999 s that the company is aware the terms and provisions of Title 1 a criminal offense to falsily, see, feditious, or fraudulent faise writing or document know, or fraudulent statement or em (2) and 108.35 (c)(1) and (2), sing of flow-sold or saddleft for or saddleft of or saddleft of or saddleft of or saddleft or or saddle
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Figure 3 –Example of FDA 2541 Cancellation of Establishment

		F	ORM APPROVED: OME	B No. 0910-	0037; EXPIRATIO	N DATE: 2-28-2	2015. (See PRA	statement on page 2.)
		OF HEALTH AND		Г	1	FOR FDA	USE ONLY	
TYPE OF SUBMISSION 2		ood and Drug Admini	stration NT REGISTRATI	- I	FCE No	TORTON	Date Receive	d by FDA
Initial Registration		3 COTABLISHME	WI KEGISTRATI	ON				
Relocation (new registration required) Enter O	current FCE: (if applicable)			- 1				
Change of Registration Information Enter Curr	rent FCE: (If applicable) 00022							
Specify Type of Change: Cancellation								
FOOD PROCESSING PLANT LOCATION	3	PREF	ERRED MAILING	ADDRE	SS Sa	me as Plant Lo	ocation	4
XYZ Co.								
1111 East St.								
City and State	0.014-407-1407		d State					
or Province (or other Subdivision) Abbotsford, Vancouver, Bri	itish Columbia	or Prov (or oth	rince er Subdivision)					
VT2 6W3 Canac								
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